REMARKS

Claims 1, 3 and 5-7 have been amended to more definitely set forth the invention and obviate the rejections. In addition, new claims 8 and 9 have been added. Support for the amendment of claims 1, 3 and 5-7, and the subject matter of new claims 8 and 9, can be found in the specification on page 3, line 25, to page 4, line 1, page 5, lines 5-8, and page 5, lines 16-18. The present amendment is deemed not to introduce new matter. Claims 1-9 are in the application.

Reconsideration is respectfully requested of the objections of claim 5, as containing grammatical errors, and claim 7, as being indefinite.

Claim 5 has been amended herein to delete the misspelling noted by the Examiner. Further, claim 7 has been amended to state that "X and Y" are "any amino acid residues other than Gly". As such, it is believed that the objection is now moot. Withdrawal of the objections is accordingly respectfully requested.

Reconsideration is respectfully requested of the rejection of Claims 5 and 7 under 35 U.S.C. §102(b) as being anticipated by Thakur, et al.

As previously stated, and as the Examiner has inherently acknowledged on page 3 of the instant Office Action, in the Thakur, et al. reference, (1) the model nucleus (mn): the product is chemically bonded with AHA (aminohexanoic acid), AHA-Lys-Lys-Gly-OPEG, etc. Moreover, this product is three peptide chains and (3) the product has a cubic triple-helix structure due to (1) or (2). Further, in this product, a transition temperature similar to native collagen is observed due to this cubic triple helix structure.

In contrast, in the present invention, (1) the stabilizer peptide is not bonded with any compound and, (2) the stabilizer peptide is only one peptide chain, and (3) the peptide does not have a triple-helix structure. Further, in the peptide, the transition temperature is not observed.

To constitute anticipation, all material elements of a claim must be found in one prior art source, *In re Marshall* 577 F2d 301, 198 USPQ 344 (CCPA 1978); *In re Kalm* 378 F2d 959, 154 USPQ 10 (CCPA 1967), which must be enabling to one skilled in the art. *Akzo N.V. v. U.S. Int. Trade Comm.* 808 F2d 1471, 1 PQ2d 1241 (CAFC 1986).

Claims 5 and 7 herein have been amended to now call for all of the distinguishing features of the present invention as discussed above in (1)-(3). These limitations are not believed to be disclosed in the cited Thakur, et al. reference. Thus, in view of the legal authorities cited above, it is respectfully submitted that the claimed nonantigenic stabilizers of the present invention now clearly distinguish from those disclosed in the Thakur, et al. reference. Consequently, the Examiner would be justified in no longer maintaining this rejection. Withdrawal of the rejection is accordingly respectfully requested.

Reconsideration is respectfully requested of the rejection of claims 1-2 and 4-7 under 35 U.S.C. §102(b) as being anticipated by Sakai Yasuo (JP 07082299, March 28, 1995, English translation included).

In the cited Japanese patent JP 07082299, it is disclosed that a peptide having a molecular weight of less than 1,000 Da is nonantigenic. However, the peptide in JP 07082299 does not act sufficiently as a stabilizer. In support of this contention, as disclosed in the abstract of Bio. Bull., 21(4), 330-334, 1998 of the inventor, Yasuo Sakai, "FreAlagin P (M.W. 200-500)", a copy of which

will be filed in due course, it is disclosed that a peptide of less than M.W. 1,000 is not ideal as a stabilizer. Moreover, no use of the peptide composition shown by the inventors in Japanese Patent Application Laid-Open No. 7-82299 as a stabilizer was anticipated, since a gelatin whose molecular weight is not more than about 10,000 was conventionally thought to have little stabilizing effect on urokinase, as stated in Japanese Patent Application Laid-Open No. 54-80406.

In the present invention, amended claims 1-4 and 6-7 now call for a nonantigenic stabilizer comprising **70 wt% or more of a single peptide chain having a molecular weight of from greater than 1,000 to not more than 20,000 Da**, which DOES sufficiently stabilize physiologically active substances. As the Examiner has recognized on page 4, second paragraph, of the instant Office Action, Yasuo Sakai fails to disclose that the peptide provided therein functions as a stabilizer for physiologically active substances. This lack of disclosure is understandable, as the peptide disclosed therein does NOT have the stabilizing properties of the present invention.

The Examiner has argued, however, that the stabilizing effect of the peptide disclosed in the Sakai reference is inherently disclosed. However, in relying upon a theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the prior art. *Ex parte Levy* 17PQ2d 1461 (BPAI 1990). The fact that a prior art article may inherently have the characteristics of the claimed product is not sufficient. *Ex parte Skinner* 2 PQ2d 1788 (BPAI 1986). Inherency must be a necessary result and not merely a possible result. *In re Oelrich* 666 F2d 578, 212 USPQ 323 (CCPA 1981).

It is respectfully submitted that the Examiner has not provided a technical reasoning sufficient to meet the standards of inherency provided in the legal authorities cited above. Further, claims 1-4 and 6-7 have been amended to now require that the nonantigenic stabilizer contains 70 wt% or more of the single peptide chain having a molecular weight of greater than 1,000 to not more than 20,000 Da, a limitation which is not disclosed in the cited Sakai reference.

The peptide composition shown in Japanese Patent Application Laid-Open No. 7-82299 further has a problem in that there is an undesirable limitation in raising the yield due to the narrow range of molecular weight (see page 2, line 27, to page 3, line 5 of the Specification). Consequently, the peptide disclosed in 7-82299 was not used as a stabilizer. In contrast, as disclosed on page 5, second paragraph, of the present application, the present inventors unexpectedly discovered that a high yield could be obtained when producing peptides having a molecular weight of greater than 1,000, as compared to producing peptides having molecular weights under 1,000, while still obtaining the beneficial stabilizing effects desired herein.

In view of the distinguishing features of the present invention, as now claimed herein, as well as the deficiencies of the cited reference cited above, it is respectfully submitted that this rejection now fails as a matter of law. Withdrawal of the rejection is accordingly respectfully requested.

Reconsideration is respectfully requested of the rejection of Claims 1-7 under 35 U.S.C. § 103(a) as being unpatentable over Sakai Yasuo in view of "Current Protocols in Molecular Biology (Vol. 2, Chapter 10, pages 10.1.1-10.18.6, 1990) or Quelle (German Patent No. 4244418A1) in view of "Current Protocols in Molecular Biology" (Vol. 2, Chapter 10, pages 10.1.1-10.18.6, 1990).

The Sakai reference is discussed above. In the instant rejection, the Examiner has recognized that the Sakai reference differs from the instant invention in that purifying the composition by gel filtration is not disclosed. Nonetheless, the Examiner indicates that column processes and reverse phase chromatography are standard procedures and the gel filtration is also a common procedure known in the art for protein purification.

A formula is not the compound nor what is patented. Patentability is not, therefore, dependent solely on the similarity of the formula of the claimed compound to that of a prior art compound. The unobviousness of its properties must also be considered. In re Papesch, 137 USPQ 43 (CCPA, 1963). Once a property of a compound has been proved, it is a relevant portion of the invention as a whole and must be considered in determining the issue of obviousness under 35 U.S.C. § 103. In re Lunsford, 148 USPQ 716 (CCPA, 1966).

In the present case, it is respectfully maintained that the applicant herein has established that the peptide of the present invention has both nonantigenic and stabilizer properties which was nowhere disclosed in the prior art. In particular, it is shown in Table 4, on page 15 of the instant specification, that no reduction of the fluorescence intensity due to antibody presence by inhibitory reaction was observed when using the peptides claimed herein, while strong inhibition was caused by raw gelatin, thermolytic gelatin and gelatin decomposed by a non-specific protease.

Having established these properties, the Examiner must consider this in determining the issue of obviousness under 35 U.S.C. § 103 in view of the above-cited authority. In this particular case, the Examiner has merely dismissed these unexpected properties obtained using the process of the present invention to obtain this particular peptide, while failing to provide specific comments as to

why the test results relied on by the applicant allegedly fail to provide support for contending that these properties exist and why they do not obviate the need for comparative tests. Consequently, it is believed that this rejection fails, as a matter of law, in view of the above authority. Withdrawal of the rejection is accordingly respectfully requested.

In view of the foregoing, it is respectfully submitted that the application is now in condition for allowance, and early action and allowance thereof is accordingly respectfully requested. In the event there is any reason why the application cannot be allowed at the present time, it is respectfully requested that the Examiner contact the undersigned at the number listed below to resolve any problems.

Respectfully submitted,

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